

DURAMECTIN- ivermectin paste

Durvet

DURAMECTIN™ (ivermectin) PASTE 1.87%

Anthelmentic & Boticide

Keep out of reach of children

For Oral use in Horses Only

Net Wt. 0.21 oz (6.08g)

Removes Worms and Bots with a single dose.

Content will treat up to 1250 lb body weight

ANADA #200-326, Approved by FDA

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. DuraMectin™ (ivermectin) Paste 1.87% provides effective treatment and control of the following parasites in horses.

Large Strongyles(adults) – *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus spp.* including *T. brevicauda* and *T. serratus* and *Craterostomum acuticaudatum*; **Small Strongyles**(adults, including those resistant to some benzimidazole class compounds) – *Coronocylus spp.* including *C. coronatus*, *C. labiatus* and *C. labratus*, *Cyathostomum spp.* including *C. catinatum* and *C. pateratum*, *Cylicocylus spp.* including *C. insigne*, *C. leptostomum*, *C. nassatus* and *C. brevicapsulatus*, *Cylicodontophorus spp.*, *Cylicostephanus spp.* including *C. calicatus*, *C. goldi*, *C. longibursatus* and *C. minutus*; **Small Strongyles** – Fourth-stage larvae; **Pinworms** (adults and fourth-stage larvae) – *Oxyuris equi*; **Ascarids**(adults and third- and fourth-stage larvae) – *Parascaris equorum*; **Hairworms**(adults) – *Trichostrongylus axei*; **Large-mouth Stomach Worms**(adults) – *Habronema muscae*; **Bots**(oral and gastric stages) – *Gasterophilus spp.* including *G. intestinalis* and *G. nasalis*; **Lungworms**(adults and fourth-stage larvae) – *Dictyocaulus arnfieldi*; **Intestinal Threadworms**(adults) – *Strongyloides westeri*; **Summer Sores** caused by *Habronema* and *Draschia spp.* cutaneous third-stage larvae; **Dermatitis** caused by *neckthreadworm* microfilariae, *Onchocerca sp.*

DOSAGE AND ADMINISTRATION: This syringe contains sufficient paste to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight.

(1) While holding plunger, turn the knurled ring on the plunger 1/4 turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking. (2) Lock the ring in place by making a 1/4 turn to the right. (3) Make sure that the horse's mouth contains no feed. (4) Remove the cover from the tip of the syringe. (5) Insert the syringe tip into the horse's mouth at the space between the teeth. (6) Depress the plunger as far as it will go, depositing paste on the back of the tongue. (7) Immediately raise the horse's head for a few seconds after dosing.

PARASITE CONTROL PROGRAM: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. DuraMectin™ (ivermectin) Paste effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by *Strongylus vulgaris*.

PRODUCT ADVANTAGES

Broad-spectrum Control – DuraMectin™ (ivermectin) Paste kills important internal parasites, including bots and the arterial stages of *S. vulgaris*, with a single dose. DuraMectin™ (ivermectin) Paste

is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

ANIMAL SAFETY: DuraMectin™ (ivermectin) Paste may be used in horses of all ages, including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility.

WARNING:

Do not use in horses intended for human consumption.

Not for use in humans. Keep this and all drugs out of reach of children. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse reactions in users, to obtain more information, or to obtain a MSDS, contact Durvet at 1-800-821-5570.

PRECAUTIONS:

DuraMectin™ (ivermectin) Paste has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Environmental Safety: Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

INFORMATION FOR HORSE OWNERS: Swelling and itching reactions after treatment with DuraMectin™ (ivermectin) Paste have occurred in horses carrying heavy infections of neck threadworm (*Onchocerca sp.*) microfilariae. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur.

Healing of summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with DuraMectin™ (ivermectin) Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

STORAGE INFORMATION: STORE BETWEEN 20° C - 25° C (68° F - 77° F). Excursions between 15° C - 30° C (59° F - 86° F) are permitted.

TAKE TIME  OBSERVE LABEL DIRECTIONS

PRECAUTIONS: DuraMectin™ (ivermectin) Paste has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Environmental Safety: Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

INFORMATION FOR HORSE OWNERS: Swelling and itching reactions after treatment with DuraMectin™ (ivermectin) Paste have occurred in horses carrying heavy infections of neck threadworm (*Onchocerca sp.* microfilariae). These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur.

Healing of summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with DuraMectin™ (ivermectin) Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

STORAGE INFORMATION: STORE BETWEEN 20° C - 25° C (68° F - 77° F). Excursions between 15° C - 30° C (59° F - 86° F) are permitted.



Keep out of reach of children.

For Oral Use In Horses Only NDC 30798-837-81

DURAMECTIN™
(ivermectin) PASTE 1.87%

Anthelmintic & Boticide

Net Wt. 0.21 oz (6.08 g)

Removes worms and bots with a single dose.
Contents will treat up to 1250 lb body weight.
ANADA# 200-326, Approved by FDA

Removes Worms & Bots





DURAMECTIN™
(ivermectin) PASTE 1.87%

Anthelmintic & Boticide

Removes Worms & Bots



Manufactured by: Bimeda-Int'l Animal Health Inc.
Duluth, Georgia, USA
Canada: Bimeda-Int'l Animal Health Inc.
Toronto, Ontario, Canada M2H 2W4
Bimeda-Int'l Animal Health Inc.
Burlington, Ontario L7R 4K1
www.durvet.com
Rev. 07.12 80U802C

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. DuraMectin™ (ivermectin) Paste provides effective treatment and control of the following parasites in horses. **Large Strongyles** (adults) - *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus* and *Craterostomum acuticaudum*; **Small Strongyles** (adults, including those resistant to some benzimidazole class compounds) - *Coronocylus* spp. including *C. coronatus*, *C. labietus* and *C. labratus*, *Cyathostomum* spp. including *C. calinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insignis*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp.; *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus* and *Petrovinema poculatum*; **Small Strongyles** - Four-stage larvae; **Pinworms** (adults and fourth-stage larvae) - *Oxyuris equi*; **Ascarids** (adults, third-stage and fourth-stage larvae) - *Parascaris equorum*; **Hairworms** (adults) - *Trichostrongylus axei*; **Large-mouth Stomach Worms** (adults) - *Habronema muscae*; **Bots** (oral and gastric stages) - *Gasterophilus* spp. including *G. intestinalis* and *G. nassalis*; **Lungworms** (adults and fourth-stage larvae) - *Dictyocaulus immitis*; **Intestinal Threadworms** (adults) - *Strongylides westeri*; **Summer Sores** caused by *Habronema* and *Draschia* spp., cutaneous third-stage larvae; Dermatitis caused by **neck threadworm** microfilariae, *Onchocerca* sp.

DOSAGE AND ADMINISTRATION: This syringe contains sufficient paste to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight.

(1) While holding plunger, turn the knurled ring on the plunger 1/4 turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking. (2) Lock the ring in place by making a 1/4 turn to the right. (3) Make sure that the horse's mouth contains no feed. (4) Remove the cover from the tip of the syringe. (5) Insert the syringe tip into the horse's mouth at the space

between the teeth. (6) Depress the plunger as far as it will go, depositing paste on the back of the tongue. (7) Immediately raise the horse's head for a few seconds after dosing.

PARASITE CONTROL PROGRAM: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. DuraMectin™ (ivermectin) Paste effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by *Strongylus vulgaris*.

PRODUCT ADVANTAGES: Broad-spectrum Control - DuraMectin™ (ivermectin) Paste kills important internal parasites, including bots and the arterial stages of *S. vulgaris*, with a single dose.

DuraMectin™ (ivermectin) Paste is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

ANIMAL SAFETY: DuraMectin™ (ivermectin) Paste may be used in horses of all ages, including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility.

WARNING: Do not use in horses intended for human consumption.

Not for use in humans. Keep this and all drugs out of reach of children. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse reactions in users, to obtain more information or to obtain MSDS, contact Durvet at 1-800-821-5570.

For Oral Use in Horses Only

NDC 30798-837-81

DURAMECTIN

(ivermectin) PASTE 1.87%

ANTHELMINTIC & BOTICIDE

For Treatment of Large Strongyles, Small Strongyles, Pinworms, Roundworms (Ascarids), Hairworms, Neck Threadworms, Large-mouth Stomach Worms and Bots. See carton or outer package for complete indications and use directions. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

ANADA# 200-326, Approved by FDA

Net Weight: 0.21 oz (6.08 g)



WARNING: Do not use in horses intended for human consumption.

Not for use in humans. Keep this and all drugs out of reach of children. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse reactions in users, to obtain more information or to obtain a MSDS, contact Durvet at 1-800-821-5570.

Store at 68-77°F (20-25°C).

Manufactured by: Bimeda-MTC Animal Health Inc.
Cambridge, Ontario, Canada N3C 2W4

For Oral Use in Horses Only

DURAMECTIN
(ivermectin) **PASTE 1.87%**
ANTHELMINTIC & BOTICIDE

For Treatment of Large Strongyles, Small Strongyles, Pinworms, Roundworms (Ascarids), Hairworms, Neck Threadworms, Large-mouth Stomach Worms and Bots. See carton or outer package for complete indications and use directions. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

ANADA# 200-326, Approved by FDA

Net Weight: 0.21 oz (6.08 g)



Distributed by: DURVET, INC.
Blue Springs, MO 64014

WARNING: Do not use in horses intended for human consumption. Not for use in humans. Keep this and all drugs out of reach of children. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse reactions in users, to obtain more information or to obtain a MSDS, contact Durvet at 1-800-821-5570.

Store at 68-77°F (20-25°C).

Manufactured by: Bimeda-MTC Animal Health Inc.
Cambridge, Ontario, Canada N3C 2W4

REV.05.11
854P026

DURAMECTIN

ivermectin paste

Product Information

| | | | |
|--------------------------------|-----------------|---------------------------|---------------|
| Product Type | OTC ANIMAL DRUG | Item Code (Source) | NDC:30798-837 |
| Route of Administration | ORAL | DEA Schedule | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D) | IVERMECTIN | 18.7 mg in 1 g |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:30798-837-83 | 12 in 1 PACKAGE | | |
| 1 | NDC:30798-837-81 | 6.08 g in 1 SYRINGE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANADA | ANADA200326 | 01/17/2007 | |

Labeler - Durvet (056387798)

Registrant - Bimeda Inc., Division of Cross Vetpharm Group (060492923)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

| | | | |
|---|--|-----------|-------------|
| Bimeda-MTC Division of Cross Vetpharm Group | | 256232216 | manufacture |
|---|--|-----------|-------------|

| Establishment | | | |
|---|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Shandong Qilu King-Phar Pharmaceutical Co. Ltd. | | 421524323 | api manufacture |

| Establishment | | | |
|---|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Zhejiang Hisun Pharmaceutical Co., Ltd. | | 654211754 | api manufacture |